

## REMARKS

Claims 19-37 have been canceled without prejudice or disclaimer and have been recast as claims 38-55. Claims 38-55 are supported throughout the specification as filed including, e.g., page 2, line 25 to page 3, line 3; page 3, line 32 to page 4, line 1; page 6, line 30 to page 8, line 1, and the original claims.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

### **I. The Rejection of Claims 19-36 under 35 U.S.C. 112, Second Paragraph**

Claims 19-36 stand rejected under 35 U.S.C. 112, second paragraph as allegedly being indefinite. The Examiner states that the step of “preparing” renders the claims unclear. This rejection is respectfully traversed.

To expedite prosecution, Applicants have amended the claims herewith. The amended claims do not recite the objected-to “preparing” step. Applicants submit that the rejection has been obviated.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

### **II. The Rejection of Claims 19, 21, 23, 28-30 and 37 under 35 U.S.C. 102(b)**

Claims 19, 21, 23, 28-30 and 37 stand rejected under 35 U.S.C. 102(b) as allegedly anticipated by Feldman et al. USPN 3,857,966 (“Feldman et al.”) taken in light of Loosen et al., USPN 5,356,637 (“Loosen et al.”). The Examiner cites Feldman et al. as teaching a method of producing a food composition, including the hydrolysis of fish protein by reacting the protein first with an alkaline protease and then with a neutral protease to obtain such benefits as protein that is soluble and bland so that it can be used in food substrates without adversely affecting clarity and consistency of texture, wherein the protein is inactivated after completion by raising the temperature, and the enzymes are preferably from *Bacillus*. Loosen et al. is cited as evidence that the alkaline protease Alcalase is derived from *Bacillus licheniformis*. This rejection is respectfully traversed.

The amended claims are directed to methods for producing a feed composition for feeding an animal, comprising hydrolysing fish meat with a neutral protease and an alkaline protease, wherein the amount of water is between 20% and 200% by weight of the fish meat, and

inactivating the proteases by heat treatment to obtain a feed composition comprising a fish protein hydrolysate, as well as methods of feeding an animal with a feed composition comprising a fish protein hydrolysate prepared by a method comprising hydrolysing fish meat with a neutral protease and an alkaline protease, wherein the amount of water is between 20% and 200% by weight of the fish meat, and inactivating the proteases by heat treatment to obtain a feed composition comprising a fish protein hydrolysate, and administering the feed composition to an animal.

In contrast, at most, Feldman et al. teaches at Example III that a “fish protein concentrate” was used to prepare a fish protein hydrolysate, which was then used in Example VI for producing a commercially available strawberry flavoured Jell-O brand gelatine dessert. Feldman, col. 3, line 66 to col. 6, line 3 and col. 6, lines 20-41. For the avoidance of doubt, in a fish protein concentrate, the protein is more concentrated than in fish meat (otherwise it wouldn’t be a concentrate). Thus, in a fish protein concentrate, some or all of the fat has been removed, for example by use of chemical solvents. Nowhere does Feldman et al. teach or suggest hydrolysis of fish meat, without further processing, as would clearly be required in order to make a “fish protein concentrate”, let alone hydrolysis of fish meat wherein the amount of water is between 20% and 200% by weight of the fish meat. Thus, Feldman et al., taken alone or in light of Loosen et al., does not teach or suggest the pending claims.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 102(b). Applicants respectfully request reconsideration and withdrawal of the rejection.

### **III. The Rejection of Claims 20, 24 and 28-36 under 35 U.S.C. 103(a)**

Claims 20, 24 and 28-36 stand rejected under 35 U.S.C. 103 as allegedly being unpatentable over Feldman et al. taken with Simpson et al., Food Chemistry vol. 61, no. ½, pages 131-138 (1998) (“Simpson et al.”) in view of Faith Jr. et al., USPN 3,697,285 (“Faith Jr. et al.”). Feldman et al. is cited as above. Simpson et al. is cited for the recognition that fish protein hydrolysates have been used in the art for pigs, fish feed, calves and pet foods, and provides the motivation to do what Feldman et al. has done in order to obtain a soluble, bland and heat stable protein. Faith Jr. et al. is cited as teaching hydrolysis of fish proteins, and further processing after enzymatic hydrolysis, as well as the use of raw fish. The Examiner contends that to start the hydrolysis using Feldman’s disclosure and with raw fish would not require more than ordinary skill. The Examiner also alleges that Simpson et al.’s disclosure of fish feed renders obvious the variety of fish recited in claim 33. This rejection is respectfully traversed.

As previously stated, the pending claims are directed to methods for producing a feed composition for feeding an animal, comprising hydrolysing fish meat with a neutral protease and an alkaline protease, wherein the amount of water is between 20% and 200% by weight of the fish meat, and inactivating the proteases by heat treatment to obtain a feed composition comprising a fish protein hydrolysate, as well as methods of feeding an animal with a feed composition comprising a fish protein hydrolysate prepared by a method comprising hydrolysing fish meat with a neutral protease and an alkaline protease, wherein the amount of water is between 20% and 200% by weight of the fish meat, and inactivating the proteases by heat treatment to obtain a feed composition comprising a fish protein hydrolysate, and administering the feed composition to an animal.

In contrast, none of Feldman et al., Simpson et al. or Faith Jr. et al. teach or suggest hydrolysis of fish meat with a neutral protease and an alkaline protease, wherein the amount of water is between 20% and 200% by weight of the fish meat.

As stated above, nowhere does Feldman et al. teach or suggest hydrolysis of fish meat, without further processing, as would clearly be required in order to make a “fish protein concentrate”, let alone hydrolysis of fish meat wherein the amount of water is between 20% and 200% by weight of the fish meat.

Simpson et al. is directed to hydrolysis of fresh and frozen shrimp with chymotrypsin or trypsin and evaluation thereof. Nowhere does Simpson et al. teach or suggest hydrolysis of fish meat, let alone hydrolysis of fish meat wherein the amount of water is between 20% and 200% by weight of the fish meat.

Neither does Faith Jr. et al. teach or suggest this claim element, nor suggest any reason to modify the teaching of Feldman et al., which is limited to manipulations of a “fish protein concentrate” or of Simpson et al., which is directed to hydrolysis of fresh and frozen shrimp with chymotrypsin or trypsin. In fact, Faith Jr. et al. teaches (column 3, line 19) that the reaction mixture utilized therein contains up to 30% by weight of solids, preferably about 10 to 20% by weight. While Faith Jr. et al. states that the solids content utilized is not critical, further guidance of an appropriate solids content according to Faith Jr. et al. is provided, e.g., in Example 1, which provides placing 10 lbs. of fresh raw hake in 83.5 lbs. (i.e., 10 gallons times 8.35 lbs. per gallon) of water containing alkaline bacterial protease. Faith Jr. et al., Example 1, especially col. 4, lines 62-67. Thus, Faith Jr. teaches that a significant excess of water as compared to fish meat is required.

In contrast, the pending claims are directed to hydrolysis conditions wherein the amount of water is between 20% and 200% by weight of the fish meat. Thus, there is no overlap of the water amounts disclosed in Faith Jr. et al., and in fact, Faith Jr. et al. teaches away from using the lower volumes of water as required by the pending claims.

For at least these reasons, none of Feldman et al., Simpson et al. and Faith Jr. et al. teach or suggest the pending claims.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103(a). Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **IV. The Rejection of Claim 37 under 35 U.S.C. 103(a)**

Claim 37 is rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Feldman et al. taken with Simpson et al. in view of Freeman et al., USPN 4,473,589 ("Freeman et al."). Feldman et al. and Simpson et al. are discussed above. Freeman et al. is cited as teaching the use of hydrolyzed fish protein as feed supplements. The Examiner contends that these disclosures render obvious feeding animals with hydrolyzed proteins as obtained from Feldman et al. and based on the fact that feeding animals with fish protein hydrolysates was already being practiced in the art when the invention was made. This rejection is respectfully traversed.

As stated above, neither Feldman et al. nor Simpson et al. teach or suggest hydrolysis of fish meat, let alone hydrolysis of fish meat wherein the amount of water is between 20% and 200% by weight of the fish meat.

Freeman et al. is directed at a method for liquefying protein from animal tissue or single cell microorganisms but does not teach that any specific enzyme or enzyme combination is to be preferred (in fact, it is stated that "in general, any proteolytic enzyme may be employed" (column 2, line 60)), and especially does not teach the specific combination of a neutral and an alkaline protease for hydrolysis of fish meat, let alone hydrolysis wherein the amount of water is between 20% and 200% by weight of the fish meat. Applicants respectfully submit that the amended claims are not obvious over Feldman et al. taken with Simpson et al. in view of Freeman et al. for at least this reason.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103(a). Applicants respectfully request reconsideration and withdrawal of the rejection.

## **V. The Rejection of Claim 25 under 35 U.S.C. 103(a)**

Claim 25 stands rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Feldman et al. taken with Simpson et al. in view of Ikeda et al., USPN 4,036,993 ("Ikeda et al.") and FR 2352498 ("FR '498"). Feldman et al. and Simpson et al. are discussed above. Ikeda et al. is cited for teaching elevating temperature to above 60 °C. FR '498 is cited as teaching heating fish to 40 °C before being subjected to enzymatic action. The Examiner contends that the temperature ranges show that determining such temperatures are within the ambit of routine skill based on the enzyme used, the type of protein and hydrolysis required. This rejection is respectfully traversed.

As stated above, nowhere does Feldman et al. nor Simpson et al. teach or suggest hydrolysis of fish meat, let alone hydrolysis of fish meat wherein the amount of water is between 20% and 200% by weight of the fish meat. The temperature treatments alleged by the Examiner to be disclosed in Ikeda and/or FR '498 do not change this conclusion, and Applicants respectfully submit that the amended claims are not obvious in view of the cited references for at least this reason.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103(a). Applicants respectfully request reconsideration and withdrawal of the rejection.

## **VI. The Rejection of Claim 22 under 35 U.S.C. 103(a)**

Claim 22 stands rejected under 35 U.S.C. 103 as allegedly being unpatentable over Feldman et al. taken with Simpson et al. in view of Xu et al., US Pub 2002/0004085 ("Xu et al."). Feldman et al. and Simpson et al. are cited as above regarding claim 19. Xu et al. is cited as teaching that GLUTENASE or NEUTRASE are neutral proteases obtained from *Bacillus amyloliquefaciens*. The Examiner contends that the use of such enzymes as the neutral protease of Feldman et al. would have been *prima facie* obvious. This rejection is respectfully traversed.

As previously stated, neither Feldman et al., nor Simpson et al., either alone or in combination with the variously cited references, teach or suggest hydrolysis of fish meat, let alone hydrolysis of fish meat wherein the amount of water is between 20% and 200% by weight of the fish meat. The enzyme sources recited in Xu et al. do not change this conclusion, and Applicants respectfully submit that the amended claims are not obvious in view of the cited references for at least this reason.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

## **VII. The Rejection of Claims 26-27 under 35 U.S.C. 103(a)**

Claims 26-27 stand rejected under 35 U.S.C. 103 as allegedly being unpatentable over Feldman et al. taken with Simpson et al. in view of Blinkovsky et al., USPN 6,187,578 ("Blinkovsky") and Olsen, USPN 4,324,805 ("Olsen"). Feldman et al. and Simpson et al. are cited as above. Blinkovsky et al. and Olsen are cited as disclosing the degree of hydrolysis. The Examiner contends that the DH claimed would have been determinable and controlled within the ambit of the routine. This rejection is respectfully traversed.

As previously stated, neither Feldman et al., nor Simpson et al., either alone or in combination with the variously cited references, teach or suggest hydrolysis of fish meat, let alone hydrolysis of fish meat wherein the amount of water is between 20% and 200% by weight of the fish meat. The degree of hydrolysis recited in Blinkovsky et al. and/or Olsen do not change this conclusion, and Applicants respectfully submit that the amended claims are not obvious in view of the cited references. Moreover, as also previously noted, the amended claims are not in the format of product-by-process claims, and respectfully submit that any rejections alleged as a result of this format have been obviated thereby.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

## **VIII. Additional Reference**

The Examiner cites Kristinsson et al. as showing a general method of enzymatic hydrolysis of salmon mince to produce fish protein hydrolysate. However, the Examiner states that Kristinsson et al. is not applied to the pending claims. Therefore, Applicants respectfully submit that no response to Kristinsson et al. is required. If a rejection over Kristinsson et al. is intended, then Applicants respectfully request that the Examiner so clarify in the next office Communication.

## **IX. Conclusion**

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

All required fees were charged to Novozymes North America, Inc.'s Deposit Account No.

50-1701 at the time of electronic filing. The USPTO is authorized to charge this Deposit Account should any additional fees be due.

Respectfully submitted,

Date: November 30, 2010

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